DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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September 29, 2015

Incereb Ltd
Paul Phillips
QA/RA Manager
Centre Of Applied Science For Health,
Institute Of Technology Tallaght
Dublin, IE DUBLIN24

Re: K151576
Trade/Device Name: Neon EEG
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY
Dated: June 4, 2015
Received: June 17, 2015

Dear Paul Phillips:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carlos L. Pena -S

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
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Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151576

Device Name
NEON EEG

Indications for Use *(Describe)*
The NEON EEG is intended to be applied directly to the patient's scalp to enable recordings of electrophysiological signals (such as EEG) on infants from birth. The NEON EEG is indicated for single use only and should be replaced after 12 hours of use.
The NEON EEG is not indicated for use with electro stimulation equipment.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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V. 510(K) SUMMARY

510(k) SUMMARY

Incereb Ltd's NEON EEG

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

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Contact Person: Paul Phillips

Date Prepared: 4th June 2015

Name of Device

NEON EEG

Common or Usual Name

Cutaneous Electrode

Classification Name/Product Code/CFR Reference

Class II, Cutaneous Electrode, Product code: GXY, 21 CFR 882.1320,

Predicate Devices

Primary Predicate: Aspect Medical Systems' BIS Bilateral Sensor (K062692)
Secondary Predicate: Aspect Medical Systems' BIS Pediatric Sensor (K041670)

Intended Use / Indications for Use

The NEON EEG is intended to be applied directly to the patient's scalp to enable recordings of electrophysiological signals (such as EEG) on infants from birth.

The NEON EEG is indicated for single use only and should be replaced after 12 hours of use.

The NEON EEG is not indicated for use with electro stimulation equipment

Technological Characteristics

The NEON EEG consists of an array of pre-gelled electrodes that are sized to fit an infant's scalp. The electrodes utilize materials that are common in sensing technology: The electrodes are screen-printed in Ag/AgCl ink on a flexible polyester substrate. The electrodes are pre-gelled with industry-standard electrode paste that provides both the intimate electrical connection and the adhesion to the scalp. The electrode array substrate has a thin layer of inert foam to provide comfort to the patient whilst the device is being worn.

The electrode array connects to a monitoring machine by an interface cable that has medically-recognized safety end fittings ("touch proof" or "D type") that cannot be inserted into an AC outlet. The safety connector is connected to the electrically and patient-isolated pre-amplifier/amplifier input of a neuro-diagnostic or neuro-monitoring equipment. All of the electrical safety features are provided by the neuro-diagnostic or neuro-monitoring equipment.

The NEON electrode array is sized to fit new-born infants and so has a reduced lead set of 5 pairs of electrodes, with each pair having an electrode on opposite sides of the head, plus a Ground and Reference. The positioning of the electrodes in the array is based upon the principles of the 10-20 placement system, with the individual electrodes labeled with their 10-20 nomenclature. The shape of the array is designed to allow as much access to the scalp as possible, so that the NEON EEG can co-exist with other monitoring requirements and to allow the free circulation of air to the infant's head and thus not contribute to cranial overheating.

An industry-standard EEG electrolyte gel is supplied in the device package to allow optional application on individual electrodes sites, should it be required to reduce the electrode impedance.

Performance Standards

The NEON EEG has been tested to the relevant parts of the following recognized performance standards:

- IEC60601-1-2:2007 - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- AAMI EC12: 2005 - Disposable ECG electrodes
- IEEE 2010:2012 - IEEE Recommended Practice for Neurofeedback Systems

In all instances, the NEON EEG functioned as intended.

Substantial Equivalence

The NEON EEG is as safe and effective as the Aspect Medical Systems' BIS Bilateral Sensor (K062692). The NEON EEG has the same intended use, main technological characteristics, and principles of operation as its predicate device. The indications for use of the primary predicate device do not indicate that it is only for adult patients, though the device sizing implies it as it would be too large for a new-born. The secondary predicate (K041670) is of the same technology as both the primary predicate and the NEON, it has just 4 electrodes in its array, to allow it to be applied to a pediatric scalp. The secondary predicate's indications for use do specifically cite pediatric use.

The NEON and the two predicate devices all share the same technology, they just differ in minor technical implementations and in the number of electrodes in their electrode array, which is a feature to enable the devices to suit the size of the scalp of the patients in their intended use/indications for use. These minor differences between the NEON EEG and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the NEON EEG is safe and effective in use. Thus, the NEON EEG is substantially equivalent.